AF IFW

Appl. No. : 09/554,167
Confirmation No. : 6758
Applicant : Thierry Gicquel, et al.

Filed : July 11, 2000
Title : REACTION VESSELS, A SET OF SUCH VESSELS, AND AN IMMUNOLOGICAL ASSAY METHOD AND APPARATUS IMPLEMENTING SUCH SETS OF VESSELS

TC/A.U. : 1641
Examiner : K. Padmanabhan

Docket No. : 072211-9011-00

I, Mary A. Hietpas, hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.

Mary A. Hietpas
Signature

October 25, 2004
Date of Signature

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APPEAL BRIEF

Sir:

Applicants have appealed from the decision dated April 20, 2004 of the Examiner finally rejecting Claims 16-17, 19-21, and 23. This Appeal Brief is submitted in triplicate in support thereof. A check for $340.00 in payment of the fee for this Appeal Brief is submitted herewith. Applicants' attorney timely filed a Notice of Appeal on September 8, 2004. Charge or credit Deposit Account No. 13-3080 with any shortage or overpayment of the fees associated with this Appeal Brief.

REAL PARTY IN INTEREST

The real party in interest is Biotrol Diagnostic, 2, rue d'Epiais, F95380 Chennevieres-les-Louvres, France.

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RELATED APPEALS AND INTERFERENCES

There are no appeals or interference proceedings in process that would directly affect or be directly affected by the Board's decision.

STATUS OF CLAIMS

Claims 6-11, 15-17, 19-21, and 23 are pending. Claims 6-11 and 15 are allowed. Claims 16-17, 19-21, and 23 stand finally rejected and appealed. Claims 1-5, 12-14, 18, and 22 were previously canceled.

STATUS OF AMENDMENTS

Applicants have not made any amendments after final rejection.

SUMMARY OF THE INVENTION

Figures 1-2 illustrate a set 26 of reaction vessels 28. The sets 26 of reaction vessels 28 are made as one-piece moldings of opaque plastics material, in particular of filled polystyrene. Each set 26 comprises eight reaction vessels 28 in alignment on a longitudinal axis 45 and connected to one another with each set 26 having two L-shaped top longitudinal rims 30 extending higher than the open top ends of the vessels 28. Page 6, lines 19-27.

Each longitudinal rim 30 of each vessel 28 includes a frustoconical orifice 32 for use in accurately positioning the set 26 in certain stations of the apparatus of the invention. Each of the outer side faces of the rims 30 has a pair of vertical ribs 34 for cooperating with means for driving the sets 26. Page 6, lines 28-33.

Each vessel 28 includes an opening 37 that is surrounded by a substantially planar rim 39 against which an opaque shoe 41 can be pressed (Figures 4 to 6), so as to prevent external light from penetrating into a photometric measuring device 43. Page 7, lines 15-22.

The rim 39 includes a space 39' between the vessels 28 and two margins 39" situated between the walls 30' of the rim 30 and the longitudinal walls 28' of the top portions of the vessels 28. Page 7, lines 23-27.

The general structure of the automatic chemiluminescence measuring apparatus 10, shown diagrammatically in Figure 3, comprises a frame 10, a turntable 12 for supporting samples to be analyzed, and a turntable 14 for supporting assay reagents, and means 16, 18 for taking

determined quantities of samples and of reagents respectively and for depositing the taken quantities into a reaction vessel. The means 16, 18 are of the same type as those described in international application WO 96/14582 and FR 96/12546, the contents of which are incorporated herein by reference. Page 8, lines 14-24.

The reagents used are of the magnetic bead type, and the apparatus 10 comprises means 20 for washing or rinsing such magnetic beads. The means 20 are of the same type as those already described in the above-specified applications having vertically-displaceable needles for sucking up and injecting liquid, together with permanent magnets located on either side of the path of the reaction vessels 28 so as to attract by magnetic attraction the magnetic beads carrying the reagents and fix them temporarily on the walls of the reaction vessels. The means 20 also have a needle for depositing a chemiluminescent substrate in the reaction vessels 28, located immediately downstream from the needles for injecting and sucking up washing liquid. Page 8, line 25-page 9, line 2.

The apparatus 10 includes photometric means 22 for optical reading purposes. The photometric means 22 comprises the photometric measuring device 43 for measuring light intensity at the wavelengths of a luminescence of the substrate used. Page 9, lines 3-5. The photometric measuring device 43, illustrated in Figures 5-6, is fixed relative to a bottom plate 47.2 and moving equipment 59. By way of example, the moving equipment 59 comprises a shutter 61, and a light guide 63 housed in an opaque rigid tubular duct 65 that opens via an opening 67 in the opaque shoe 41. A rail 67 provides guidance between a low position as shown in Figure 5 in which the shutter 61 optically isolates the photometric measuring device 43 from the light guide 63 and a high position as shown in Figure 6 in which the shutter 61 is retracted so as to allow communication between the light guide 63 and the photometric measuring device 43. Page 10, line 36-page 11, line 11.

The output from the photometric measuring device 43 is connected via interface and matching means to a computer for monitoring the machine, making use of the results, and/or managing the results. Page 9, line 35-page 10, line 7.

The apparatus 10 also includes means 24 for displacing the sets 26 of reaction vessels 28 along a path. Page 10, lines 21-25.

The apparatus 10 includes a light source 57, e.g. a light-emitting diode (LED), for verifying the optical isolation of the temporary dark chamber formed when the photometric

measuring device 43 contacts the planar rim 39 of the vessel 28 being measured. Page 10, lines 31-35.

The apparatus operates as follows. The apparatus 10 is loaded with reagents and the substrate and with the samples (serum) to be tested. Page 11, lines 31-35.

During a first revolution, the vessels 28 of the sets 26 receive from the device 16 the samples to be tested. The sets 26 are driven by the belt 40. Page 11, line 36-page 12, line 2.

During a second revolution, the vessels 28 receive the reagents from the device 18. Page 12, lines 3-4.

During a third revolution, the means 20 wash the magnetic beads and the luminescent substrate is inserted. Page 12, lines 5-7.

During the last revolution, the result of the test is revealed and then read. To read the luminescence of each vessel 28, the darkness level is initially calibrated, i.e. the voltage available at the outlet from the photometric measuring device 43 is read while the shutter 61 is closed (low position shown in Figure 5); then an actuator presses the moving equipment 59 against the inlet 37 of a vessel 28. More precisely, a light-proof shoe 41 is pressed against the planar rim 39 of the vessel 28 to be read. A positioning stud 51 ensures accurate positioning with the opening 67 of the shoe 41 being superposed on the inlet 37 of the vessel 28. Page 12, lines 8-19.

In one embodiment, the set 26 of vessels 28 rises and lifts the moving equipment. In the preferred embodiment, an actuator lowers the lower plate 47.2, thereby causing the moving equipment 59 to rise relative to the plate 47. The movement of the moving equipment 59 causes the shutter to open and enables the luminescence present in the vessel 28 to be measured. Page 12, lines 20-27.

The moving equipment 59 moves down relative to the plate 47.2 (as shown in Figure 5), and the light source 57 is switched on, after which a new measurement is performed to verify the light-tightness of the temporary dark chamber formed by the photometric assembly 22 and the vessel 28 under measurement. If the luminescence value obtained during the light-tightness measurement is greater than the value obtained during the measurement proper, it is determined that the result of the measurement is not reliable. The result of the test is rejected, and the test is repeated using the same reaction mixture again with the same sample and the same reagent as deposited in a new vessel 28. Page 12, line 28-page 13, line 3.

Testing for light-tightness can be performed prior to measuring luminescence without thereby going beyond the scope of the present invention. Page 13, lines 4-6.

Similarly, measuring the voltage level at the output from the photometric measuring device 43 while the shutter 61 is closed can be performed periodically, and is not required for all of the measurements. Page 13, lines 7-10.

STATEMENT OF THE ISSUES

1. Whether Claims 16-17, 19-21, and 23 are unpatentable under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,849,247 ("Uzan") in view of U.S. Patent No. 5,048,957 ("Berthold"), U.S. Patent No. 5,643,535 ("Smethers"), U.S. Patent No. 5,637,874 ("Honzawa"), and U.S. Patent No. 5,825,486 ("Zavislan")?

GROUPING OF THE CLAIMS

The rejected claims do not stand or fall together, and the following groups are separately patentable:

Group I: Claim 16,

Group II: Claims 17 and 19-21, and

Group III: Claim 23.

THE REFERENCES

U.S. Patent No. 5,849,247 ("Uzan")

Uzan discloses a reaction module for an automatic immunological assay apparatus. Abstract. The reaction module is a single piece of transparent plastic material comprising eight reaction wells aligned in a single row. Fig. 4; Col. 3, lines 26-28. After a sample, reagent(s) and substrate have been deposited in a reaction well, the results of the assay are obtained by passing a light beam through the reaction well towards a detector for determining the result of the assay on the basis of the light intensity received by the detector. Col. 7, lines 6-23. The reaction modules are designed to slide between rails that define a U-shaped track and run from an automatic feed device to a device for ejecting the wells after use. Abstract.

U.S. Patent No. 5,048,957 ("Berthold")

Berthold discloses a specimen rack with insertable cuvettes for performing assays of chemiluminescence or bioluminescence. Col. 1, lines 6-8. The specimen rack is composed of a flat, substantially cuboid block of radiopaque material with a number of bores arranged in a matrix-like pattern that extend vertically through the block. Fig. 1; Col. 4, lines 21-28. The bores are designed to hold single cuvettes or strip-racks that consist of cuvettes connected by a strip of radiopaque material. Col. 4, lines 32-38; Col. 3, lines 46-48. The bores have a reduced cross section at their lower end thus forming an annular shoulder upon which the bottom of a cuvette rests. Col. 4, lines 47-54. Each cuvette is continuously opaquely shielded from scattering radiation from adjacent cuvettes except for the region defined by the lower opening cross section oriented towards a detector. Abstract; Col. 4, lines 47-49.

U.S. Patent No. 5,643,535 ("Smethers")

Smethers discloses a luminometer that has a platform for carrying an array of sample wells, where each well has an upper edge structure defining a window through which light can be received. Col. 2, lines 26-28; Col. 7, lines 14-15. The wells are typically formed from opaque polystyrene. Col. 6, lines 26-27. The photodetector assembly of the luminometer includes a stage, a photodetection head having a detection aperture permitting passage of light therethrough, a means for mounting the photodetection head to the stage that permits movement of the head in a direction substantially normal to the direction of the array of sample wells and photodetector assembly movement, and a means for biasing the photodetection head toward a selected sample well so that the detection aperture is substantially isolated from light emitted from adjacent wells. Abstract.

U.S. Patent No. 5,637,874 ("Honzawa")

Honzawa discloses a chemiluminescence measuring apparatus comprising a box-like housing having an opening at a top surface, a cover provided at the top surface having a through hole that allows a distal end of a syringe containing a luminous reagent to be introduced into the interior of the housing, a hollow chamber with a side wall opening being disposed in the housing and partially enclosing a micro-sample tube containing a sample solution, and a photo-sensing unit being disposed in the housing for detecting luminescence from the micro-sample tube via the opening of the hollow chamber. Col. 1, lines 51-67; Col. 2, lines 1-3. The hollow chamber 33 includes a rotating cylindrical hollow chamber 370 having an opening 37. Col. 5, lines 41-44. The optical path between the photo-sensing unit 40 and the micro-sample tube 21 is opened

when the position of the opening 38 and the position of the opening 37 coincide with each other. Col. 5, lines 44-47.

U.S. Patent No. 5,825,486 ("Zavislan")

Zavislan discloses a spectrophotometer including electrical components mounted in a module 260. Col. 10, lines 13-15. The module 260 is supported within a housing 262. Col. 10, lines 15-16. The module 260 includes a wall 74 having an extension 264. Col. 10, lines 16-17. The extension 260 includes a first cavity 266 that supports a lamp 268 and a second cavity 270 that supports a cuvette 271. Col. 10, lines 17-19. The walls of the cuvette 271 are transparent, and the cuvette 271 includes an opaque cover 274, which pivots downwardly to close the cuvette 271. Col. 10, lines 20-22. Upon closure of the cover 274, the lamp 268 is illuminated and projects through the sample in the cuvette 271 for spectral measurement. Col. 10, lines 22-30.

THE REJECTION

The Examiner rejected Claims 16-17, 19-21, and 23 under 35 U.S.C. § 103 as being unpatentable over Uzan in view of Berthold, Smethers, Honzawa, and Zavislan. The Examiner contends that Uzan discloses

> an automatic immunological assay comprising reaction wells, means for supporting samples to be analyzed, means for supporting reagents, means for taking determined quantities of samples and of reagents and depositing them in reaction wells, means for reading assay results, and means for displacing the wells (col. 1). The reference also teaches means for washing or rinsing the beads in the vessels (col. 2). Furthermore, the reaction modules are formed as single pieces by molding plastics, each comprising eight reaction wells (col. 3). In addition, the reference also teaches the use of a pivoting arm that is used to position reagents or samples (col. 5). A substrate specific to a specific enzyme in the reaction well is deposited in the well, and enzyme interaction takes place, which is followed by reading of the results (col. 7). Uzan et al. also teach horizontal plates for receiving or supporting the washing means and photometric means.

Office Action, dated April 20, 2004, page 3.

The Examiner acknowledged that Uzan does not teach or suggest "the specific use of vessels with opaque sides, a chemiluminescent substance as the enzyme in the reaction well, a shutter mechanism, or a light proof shoe." Office Action, dated April 20, 2004, page 3.

The Examiner also contends that Berthold discloses "a specimen rack made of radiopaque material, such that each cuvette, except for a region defined by the lower opening cross section of the through chambers and their upper filling opening, is continuously shielded from scattering radiation from adjacent cuvettes (abstract). The Examiner acknowledged that Berthold does not teach or suggest "the use of a chemiluminescent substance, a shutter, or a light proof shoe." Office Action, dated April 20, 2004, page 3.

The Examiner also contends that Smethers discloses

> a luminometer with reduced sample crosstalk comprising an array of sample wells, a photodetector assembly, and means for moving the sample tray and photodetector (abstract). Each well in the array has a structure defining a window through which light can be emitted (col. 2). The reference also teaches the use of luminescence, either chemiluminescence or bioluminescence, as an effective for the determination of a variety of analytes (col. 1). Smethers et al. also teach a photodetector internal-calibration system. This includes a sealed chamber with a light source contained therein, a photosensor, and means for directing the light emitted from the light source to the photodetector when the assembly is positioned at an internal calibration system station. In addition, the reference teaches an external calibration system (col. 2).

Office Action, dated April 20, 2004, pages 3-4.

The Examiner acknowledged that Smethers does not teach or suggest "the use of a shutter or lightproof shoe." Office Action, dated April 20, 2004, page 4.

The Examiner also contends that Honzawa discloses

> a chemiluminescence measuring apparatus comprising a shutter mechanism. The shutter mechanism, when closed, will create a temporary dark chamber that is proof against external light, at which time the photodetector will measure the luminescence. Furthermore, the shutter mechanism includes a rotating hollow chamber, which houses the vessel, a dark box, which can be interpreted as a light-proof shoe, that encompasses the read window, and a photosensing unit, which includes a photomultiplier (col. 2). The rotation of the cylindrical member determines when the shutter opens and closes, and correspondingly when the luminescence is measured. In addition, the dark box portion of the lightproof shoe has an opening that creates an optical path between the vessel and photometric means (col. 2).

Office Action, dated April 20, 2004, page 4.

The Examiner acknowledged that Honzawa does not teach or suggest "a light proof shoe directly pressed against the vessel." Office Action, dated April 20, 2004, page 4.

The Examiner further contends that Zavislan discloses "a module comprising a cuvette which holds a liquid sample, which cuvette has an opaque cover pressed against it." Office Action, dated April 20, 2004, page 4.

The Examiner contends that

> it would have been *prima facie* obvious to one of ordinary skill at the time of the invention to use the opaque vessel of Berthold et al. and the chemiluminescent label of Smethers et al. with the vessel of Uzan et al. One would have been motivated to use a chemiluminescent label with the vessel of Uzan et al. because they teach the generic use of an enzyme specific for a substrate that produces a detectable signal. Chemiluminescent labels are widely used for this purpose, and would have been an obvious choice for use in the vessel. In addition, one would have been motivated to use a vessel or well with opaque sides to reduce the cross talk or contamination of reading between cells. Since opaque sides limit the emission of light to the top-filling opening, other wells will not be contaminated with the results of adjacent wells.

Office Action, dated April 20, 2004, pages 4-5.

The Examiner continues

> it would have further been *prima facie* obvious to one of ordinary skill at the time of the invention to use the shutter mechanism and lightproof shoe of Honzawa et

al. with the modified vessel of Uzan et al. One would have been motivated to use the shutter mechanism to create a temporary dark chamber to obtain a luminescence reading. Furthermore, a shutter mechanism is well known in the art, as the majority of commercially available photometry instruments utilize these mechanisms to take luminescence readings. In addition, a lightproof shoe can be interpreted as any enclosure or part that is impermeable to light. Once again, this is well known in the art, as all photometers utilize this technique. It would have been obvious to use the calibration system of Smethers et al. with the modified device of Uzan et al. in order to ensure accurate readings for the samples. Calibration is also well known in the art, as background readings need to be subtracted to get true luminescence readings. In addition, it would have been obvious at the time of the invention to arrange the light source such that the filling opening of the wells are also the window for reading the intensity of light, since it has been held that rearranging parts of an invention involves only routing skill in the art. *In re Japikse*, 86 USPQ 70. Finally, it would have been obvious to one of ordinary skill in the art at the time of the invention to press the opaque shoe directly against the vessel as in Zavislan et al. because direct, as opposed to indirect, contact ensures a tighter seal, which would keep light out in a more effective and efficient manner.

Office Action, dated April 20, 2004, pages 5-6.

The Examiner, in the Advisory Action dated August 5, 2004, indicated that

Zavislan was only relied upon for teaching an opaque cover direclty [sic] pressed against a sample cuvette, and as a secondary reference under 35 USC 103, it is not required to teach all the limitations of the claims, as the other limitations have been taught by the combination of Uzan, Berthold, Smethers, and Honzawa. While applicant may be correct in asserting that Zavislan does not form a temporary dark chamber, it is noted that the combination of references cited above does teach that limitation, and Zavislan only need teach an opaque cover. Further, while applicant may also be correct in asserting that Zavislan allows light to pass through the cuvette, the opaque cover still performs the function of excluding external light from entering the cuvette. As such, by combining the opaque cover of Zavislan with the other references, one arrives at the claimed invention. Further, one would have been motivated to use the opaque cover of Zavislan because it ensures the elimination of unwanted light (light other than that from the excitation source) from passing through the sample.

ARGUMENT

Relevant Law

The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. In re Keller, 642 F.2d 413, 425, 208 U.S.P.Q. 871, 881 (CCPA 1981). In proceedings before the Patent and Trademark Office, the Examiner bears

the burden of presenting a *prima facie* case of obviousness based upon the prior art. In re Fritch, 972 F.2d 1260, 1265, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992); In re Fine, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. Id. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (CCPA 1974); MPEP §§706.02(j), 2143.03.

In establishing a *prima facie* case of obviousness, it is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. Ex parte Clapp, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from Appellant's disclosure. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 U.S.P.Q.2d 1434, 1439 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988); In re Vaeck, 947 F.2d at 493, 20 U.S.P.Q.2d at 1442; MPEP §2143. The Examiner can only establish a *prima facie* case of obviousness by pointing out some objective teaching in the prior art references themselves that would lead one of ordinary skill in the art to combine the relevant teachings and the references. In re Fine, 837 F.2d at 1074, 5 U.S.P.Q.2d at 1598-99; In re Jones, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992); MPEP §2143.01.

In addition, the mere fact that the prior art structure could be modified does not make such a modification obvious unless the prior art suggests the desirability of doing so. In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984); In re Mills, 916 F.2d 680, 682, 16 U.S.P.Q.2d 1430, 1432 (Fed. Cir. 1990); MPEP §2143.01.

Further, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d at 902, 221 U.S.P.Q. at 1127; MPEP §2143.01.

During examination of an application, the Examiner must determine what is analogous prior art when applying a 35 U.S.C. § 103 rejection. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." In re Oetiker, 977 F.2d 1443, 1446 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); M.P.E.P. § 2141.01(a).

Claim Rejections under 35 U.S.C. § 103(a)

Group I

The claim of Group I, Claim 16, is patentable separately from the claims of the other groups, as described below in more detail.

Independent Claim 16 defines a reaction vessel assembly for an automatic chemiluminescence measuring apparatus for immunological assay which includes a photometric device. The assembly comprises a vessel comprising walls for receiving a sample to be tested, a test reagent, and a substrate coupled with a chemiluminescent substance, and a filling opening, wherein the walls are proof against any light emitted by the chemiluminescent substance, and the filling opening corresponds to a window for reading an intensity of any light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate, and wherein the filling opening is completely surrounded by a planar rim; and a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device.

Uzan does not teach or suggest, as acknowledged by the Examiner, a chemiluminescent substance, a vessel comprising walls that are proof against any light emitted by the chemiluminescent substance, and a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device. Office Action dated April 20, 2004, page 3.

Berthold does not cure the deficiencies of Uzan. Berthold does not teach or suggest, as acknowledged by the Examiner, a chemiluminescent substance and a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device. Office Action dated April 20, 2004, page 3.

Berthold also does not teach or suggest a filling opening that corresponds to a window for reading an intensity of light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate. Rather, Berthold discloses an opaque specimen rack 10 that holds transparent cuvettes 20. The bottom of the specimen rack provides an opening for the detector 40 to detect radiation from the transparent cuvette. Abstract; Col. 4, lines 47-58.

Smethers does not cure the deficiencies of Uzan and Berthold. Smethers does not teach or suggest, as acknowledged by the Examiner, a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device. Office Action dated April 20, 2004, page 4.

Honzawa does not cure the deficiencies of Uzan, Berthold, and Smethers. Honzawa does not teach or suggest, as acknowledged by the Examiner, a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device. Office Action dated April 20, 2004, page 4.

Honzawa also does not teach or suggest, a filling opening that corresponds to a window for reading an intensity of light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate. Rather, Honzawa discloses a chemiluminescence measuring apparatus including a box-like housing 1 having an opening 15 at a top surface, a cover 6 provided at the top surface having a through hole that allows a distal end of a syringe 42 containing a luminous reagent to be introduced into the interior of the housing, a hollow chamber 33 with a side wall opening 38 being disposed in the housing and partially enclosing a micro-sample tube 21 containing a sample solution, and a photo-sensing unit 40 being disposed in the housing for detecting luminescence from the micro-sample tube via the opening 38 of the hollow chamber 33. Col. 1, lines 51-67; Col. 2, lines 1-3. The hollow chamber 33 includes a rotating cylindrical hollow chamber 370 having an opening 37. Col. 5, lines 41-44. The optical path

between the photo-sensing unit 40 and the micro-sample tube 21 is opened when the position of the opening 38 and the position of the opening 37 coincide with each other. Col. 5, lines 44-47.

Zavislan does not cure the deficiencies of Uzan, Berthold, Smethers, and Honzawa. Zavislan does not teach or suggest a filling opening that corresponds to a window for reading an intensity of light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate and a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device. Rather, Zavislan discloses a spectrophotometer including electrical components mounted in a module 260. Col. 10, lines 13-15. The module 260 is supported within a housing 262. Col. 10, lines 15-16. The module 260 includes a wall 74 having an extension 264. Col. 10, lines 16-17. The extension 260 includes a first cavity 266 that supports a lamp 268 and a second cavity 270 that supports a cuvette 271. Col. 10, lines 17-19. The walls of the cuvette 271 are transparent, and the cuvette 271 includes an opaque cover 274, which pivots downwardly to close the cuvette 271. Col. 10, lines 20-22. Upon closure of the cover 274, the lamp 268 is illuminated and projects through the sample in the cuvette 271 for spectral measurement. Col. 10, lines 22-30; Fig. 23. Specifically, the opaque cover 274 does not include a central opening for passing light between the vessel and the photometric device.

Additionally, there is no suggestion or motivation to combine the five asserted reference teachings. First, there is no suggestion to combine the teachings of Uzan with Berthold, Smethers, and Honzawa because the Uzan apparatus is designed specifically for absorbency measurements. The reaction modules in Uzan are transparent so that light from a light beam can pass through each reaction well to a detector. Col. 7, lines 6-23. In contrast, the devices of Berthold, Smethers, and Honzawa are designed to measure emission rather than absorbency. Emission studies require that ambient light be reduced as much as possible from the detector during analysis. Therefore, Berthold, Smethers, and Honzawa teach away from Uzan because the devices of Berthold, Smethers, and Honzawa teach specific ways to attempt to reduce the ambient light around a particular sample being tested. Furthermore, creating an automated system to measure emission rather than absorbency requires a sophisticated detector system and reaction vessel so that a dark chamber can be formed with each reaction well as the vessel passes by the detector during transport along a path.

In addition, there is no suggestion to combine the teachings of Uzan with Berthold, Smethers, Honzawa, and Zavislan because Uzan teaches an automatic apparatus for immunological assay. The devices in Berthold, Smethers, Honzawa, and Zavislan are not automatic systems and the unique operation of each device cannot be modified for use in the automatic apparatus of Uzan. Each device of Berthold, Smethers, Honzawa, and Zavislan require a unique structure for its respective operation.

Second, there is no suggestion to combine the teachings of Zavislan with Berthold, Smethers, and Honzawa because the Zavislan device is a spectrophotometer, which measures optical density or spectral absorption. These measurements require that a light beam be projected through the test sample to a photodetector. In contrast, the devices of Berthold, Smethers, and Honzawa reject the notion of additional light as discussed above. Therefore, Zavislan teaches away from being combined with Berthold, Smethers, and Honzawa.

The Examiner indicated in the Advisory Action that "Zavislan only need teach an opaque cover... and by combining the opaque cover of Zavislan with the other references, one arrives at the claimed invention." The opaque cover of Zavislan does not satisfy the claimed requirement of a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device. In addition and as noted above, there is no suggestion or motivation to combine the teachings of Zavislan with Berthold, Smethers, and Honzawa.

The Examiner further indicated in the Advisory Action that "one would have been motivated to use the opaque cover of Zavislan because it ensures the elimination of unwanted light (light other than that from the excitation source) from passing through the sample." The Examiner cannot ignore the fact that the purpose of the Zavislan device requires that light pass through the test sample and through the transparent wall of the cuvette, in order to get a measurement. The Examiner must consider the prior art reference as a whole, including portions that would lead away from the claimed invention. M.P.E.P. § 2141.02. As noted above, there is no suggestion or motivation to combine the teachings of Zavislan with Berthold, Smethers, and Honzawa.

Accordingly, the Examiner has not presented a *prima facie* case of obviousness because the five prior art references when combined do not teach or suggest all of the claim limitations.

Specifically, the Examiner has not identified a reference or combination of references that disclose a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device.

For at least the reasons noted above, Uzan combined with Berthold, Smethers, Honzawa, and Zavislan does not teach or suggest the subject matter of Claim 16. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 16 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 16 is allowable.

Group II

The claims of Group II, Claims 17 and 19-21, are patentable separately from the other claims because these claims do not include all the limitations of the other claims and because these claims specify an automated chemiluminescent apparatus for immunological assay. More specifically, Claims 17 and 19-21 are patentable because there is no teaching, suggestion or incentive to provide the claimed automated chemiluminescent apparatus, as discussed below in more detail.

Uzan does not teach or suggest, as acknowledged by the Examiner, a chemiluminescent substance, a vessel comprising walls that are proof against any light emitted by the chemiluminescent substance, and a light-proof shoe provided with a central opening for passing light between the vessel and the photometric means and being directly pressed against the planar rim. Office Action dated April 20, 2004, page 3.

Berthold does not cure the deficiencies of Uzan. Berthold does not teach or suggest, as acknowledged by the Examiner, a chemiluminescent substance and a light-proof shoe provided with a central opening for passing light between the vessel and the photometric means and being directly pressed against the planar rim. Office Action dated April 20, 2004, page 3.

Berthold also does not teach or suggest means for supporting, guiding, and stepwise displacement of vessels, or of sets of reaction vessels along a path having a predetermined number of positions, means for washing the vessels, means for forming a temporary dark chamber with the vessel, the temporary dark chamber being proof against external light, the dark chamber having photometric means for measuring an intensity of light, and a filling opening that

corresponds to a window for reading an intensity of light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate. Rather, Berthold discloses an opaque specimen rack 10 that holds transparent cuvettes 20. The bottom of the specimen rack provides an opening for the detector 40 to detect radiation from the transparent cuvette. Abstract; Col. 4, lines 47-58. Berthold does not disclose that the specimen rack is transported along a path or that a temporary dark chamber with the vessel is formed.

Smethers does not cure the deficiencies of Uzan and Berthold. Smethers does not teach or suggest, as acknowledged by the Examiner, a light-proof shoe provided with a central opening for passing light between the vessel and the photometric means and being directly pressed against the planar rim. Office Action dated April 20, 2004, page 4.

Smethers also does not teach or suggest means for supporting, guiding, and stepwise displacement of vessels, or of sets of reaction vessels along a path having a predetermined number of positions and means for washing the vessels. Rather, Smethers discloses a luminometer 10 that has a platform for carrying an array of sample wells. Col. 2, lines 26-28; Col. 7, lines 14-15. The luminometer 10 requires manual operation of a handle 22, which controls operation of a door for sealing the opening 20 against light entry into the luminometer chamber. Col. 4, lines 34-36.

Honzawa does not cure the deficiencies of Uzan, Berthold, and Smethers. Honzawa does not teach or suggest, as acknowledged by the Examiner, a light-proof shoe provided with a central opening for passing light between the vessel and the photometric means and being directly pressed against the planar rim. Office Action dated April 20, 2004, page 4.

Honzawa also does not teach or suggest means for supporting, guiding, and stepwise displacement of vessels, or of sets of reaction vessels along a path having a predetermined number of positions, means for washing the vessels, and a filling opening that corresponds to a window for reading an intensity of light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate. Rather, Honzawa discloses a manual chemiluminescence measuring apparatus including a box-like housing 1 having an opening 15 at a top surface, a cover 6 provided at the top surface having a through hole that allows a distal end of a syringe 42 containing a luminous reagent to be introduced into the interior of the housing, a hollow chamber 33 with a side wall opening 38 being disposed in the housing and partially enclosing a micro-sample tube 21 containing a sample solution, and a photo-sensing unit 40

being disposed in the housing for detecting luminescence from the micro-sample tube via the opening 38 of the hollow chamber 33. Col. 1, lines 51-67; Col. 2, lines 1-3. The hollow chamber 33 includes a rotating cylindrical hollow chamber 370 having an opening 37. Col. 5, lines 41-44. The optical path between the photo-sensing unit 40 and the micro-sample tube 21 is opened when the position of the opening 38 and the position of the opening 37 coincide with each other. Col. 5, lines 44-47.

Zavislan does not cure the deficiencies of Uzan, Berthold, Smethers, and Honzawa. Zavislan does not teach or suggest means for supporting, guiding, and stepwise displacement of vessels, or of sets of reaction vessels along a path having a predetermined number of positions, means for washing the vessels, a filling opening that corresponds to a window for reading an intensity of light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate and a light-proof shoe provided with a central opening for passing light between the vessel and the photometric means and being directly pressed against the planar rim. Rather, Zavislan discloses a spectrophotometer including electrical components mounted in a module 260. Col. 10, lines 13-15. The module 260 is supported within a housing 262. Col. 10, lines 15-16. The module 260 includes a wall 74 having an extension 264. Col. 10, lines 16-17. The extension 260 includes a first cavity 266 that supports a lamp 268 and a second cavity 270 that supports a cuvette 271. Col. 10, lines 17-19. The walls of the cuvette 271 are transparent, and the cuvette 271 includes an opaque cover 274, which pivots downwardly to close the cuvette 271. Col. 10, lines 20-22. Upon closure of the cover 274, the lamp 268 is illuminated and projects through the sample in the cuvette 271 for spectral measurement. Col. 10, lines 22-30; Fig. 23. Specifically, the opaque cover 274 does not include a central opening for passing light between the vessel and the photometric device.

Additionally, there is no suggestion or motivation to combine the five asserted reference teachings. First, there is no suggestion to combine the teachings of Uzan with Berthold, Smethers, and Honzawa because the Uzan apparatus is designed specifically for absorbency measurements. The reaction modules in Uzan are transparent so that light from a light beam can pass through each reaction well to a detector. Col. 7, lines 6-23. In contrast, the devices of Berthold, Smethers, and Honzawa are designed to measure emission rather than absorbency. Emission studies require that ambient light be reduced as much as possible from the detector during analysis. Therefore, Berthold, Smethers, and Honzawa teach away from Uzan because

the devices of Berthold, Smethers, and Honzawa teach specific ways to attempt to reduce the ambient light around a particular sample being tested. Furthermore, creating an automated system to measure emission rather than absorbency requires a sophisticated detector system and reaction vessel so that a dark chamber can be formed with each reaction well as the vessel passes by the detector during transport along a path.

In addition, there is no suggestion to combine the teachings of Uzan with Berthold, Smethers, Honzawa, and Zavislan because Uzan teaches an automatic apparatus for immunological assay. The devices in Berthold, Smethers, Honzawa, and Zavislan are not automatic systems and the unique operation of each device cannot be modified for use in the automatic apparatus of Uzan. Each device of Berthold, Smethers, Honzawa, and Zavislan require a unique structure for its respective operation.

Second, there is no suggestion to combine the teachings of Zavislan with Berthold, Smethers, and Honzawa because the Zavislan device is a spectrophotometer, which measures optical density or spectral absorption. These measurements require that a light beam be projected through the test sample to a photodetector. In contrast, the devices of Berthold, Smethers, and Honzawa reject the notion of additional light as discussed above. Therefore, Zavislan teaches away from being combined with Berthold, Smethers, and Honzawa.

The Examiner indicated in the Advisory Action that "Zavislan only need teach an opaque cover... and by combining the opaque cover of Zavislan with the other references, one arrives at the claimed invention." The opaque cover of Zavislan does not satisfy the claimed requirement of a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device. In addition and as noted above, there is no suggestion or motivation to combine the teachings of Zavislan with Berthold, Smethers, and Honzawa.

The Examiner further indicated in the Advisory Action that "one would have been motivated to use the opaque cover of Zavislan because it ensures the elimination of unwanted light (light other than that from the excitation source) from passing through the sample." The Examiner may be correct in this statement, but the Examiner cannot ignore the fact that the purpose of the Zavislan device requires that light pass through the test sample and through the transparent wall of the cuvette, in order to get a measurement. The Examiner must consider the

prior art reference as a whole, including portions that would lead away from the claimed invention. M.P.E.P. § 2141.02. As noted above, there is no suggestion or motivation to combine the teachings of Zavislan with Berthold, Smethers, and Honzawa.

Accordingly, the Examiner has not presented a *prima facie* case of obviousness because the prior art references when combined do not teach or suggest all of the claim limitations. Specifically, the Examiner has not identified a reference or combination of references that disclose a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device.

For at least the reasons noted above, Uzan combined with Berthold, Smethers, Honzawa, and Zavislan does not teach or suggest the subject matter of Claim 17. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 17 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 17 is allowable. Claims 19-21 depend from independent Claim 17, and are therefore allowable for at least the reasons Claim 17 is allowable.

Group III

The claim of Group III, Claim 23, is patentable separately from the other claims because this claim does not include all the limitations of the other claims and because this claim specifies a method for performing immunological assays that detects light emitted by a reaction mixture. More specifically, Claim 23 is patentable because there is no teaching, suggestion or incentive to provide the claimed method, as discussed below in more detail.

Claim 23 depends from independent Claim 17. As noted above, Uzan, Berthold, Smethers, Honzawa, and Zavislan do not teach or suggest the subject matter of Claim 17. Claim 23 further specifies a method for performing immunological assays that detects light emitted by a reaction mixture consisting of a sample, a reagent and a chemiluminescent substance, said method being performed with an automated chemiluminescent apparatus as set forth in claim 17, said method comprising combining a sample and a reagent in a chamber of the reaction vessel having a filling opening; adding a chemiluminescent substance to the chamber; pressing a detector directly against the filling opening; measuring the light emitted from the chamber when the detector is pressed against the filling opening to provide a first reading; illuminating a light

source external to the chamber; measuring the light emitted from the chamber with the light source illuminated to provide a second reading; and comparing the first reading and the second reading to determine the light-tightness of the chamber.

Uzan does not teach or suggest, as acknowledged by the Examiner, adding a chemiluminescent substance to the chamber and pressing a detector directly against the filling opening. Office Action dated April 20, 2004, page 3.

Uzan also does not teach or suggest measuring the light emitted from the chamber when the detector is pressed against the filling opening to provide a first reading, measuring the light emitted from the chamber with the light source illuminated to provide a second reading, and comparing the first reading and the second reading to determine the light-tightness of the chamber. Rather, Uzan discloses an apparatus that is designed specifically for absorbency measurements. The reaction modules in Uzan are transparent so that light from a light beam can pass through each reaction well to a detector. Col. 7, lines 6-23. Uzan does not disclose pressing the detector directly against the filling opening or taking a plurality of readings to determine the light-tightness of the chamber.

Berthold does not cure the deficiencies of Uzan. Berthold does not teach or suggest, as acknowledged by the Examiner, adding a chemiluminescent substance to the chamber and pressing a detector directly against the filling opening. Office Action dated April 20, 2004, page 3.

Berthold also does not teach or suggest measuring the light emitted from the chamber when the detector is pressed against the filling opening to provide a first reading, illuminating a light source external to the chamber, measuring the light emitted from the chamber with the light source illuminated to provide a second reading, and comparing the first reading and the second reading to determine the light-tightness of the chamber. Rather, Berthold discloses an opaque specimen rack 10 that holds transparent cuvettes 20. The bottom of the specimen rack provides an opening for the detector 40 to detect radiation from the transparent cuvette. Abstract; Col. 4, lines 47-58. Berthold does not disclose pressing the detector directly against the filling opening because the detector is positioned at the bottom of the cuvette. Berthold also does not disclose the act of comparing a plurality of readings to determine light-tightness of a chamber.

Smethers does not cure the deficiencies of Uzan and Berthold. Smethers does not teach or suggest, as acknowledged by the Examiner, pressing a detector directly against the filling opening. Office Action dated April 20, 2004, page 4.

Smethers also does not teach or suggest measuring the light emitted from the chamber when the detector is pressed against the filling opening to provide a first reading, illuminating a light source external to the chamber, measuring the light emitted from the chamber with the light source illuminated to provide a second reading, and comparing the first reading and the second reading to determine the light-tightness of the chamber. Rather, Smethers discloses a technique for calibrating the photodetection head of the luminometer 10 using a calibration unit 104. Col. 9, lines 4-7. This method of calibration of the photodetection head does not determine the light-tightness of a chamber.

Honzawa does not cure the deficiencies of Uzan, Berthold, and Smethers. Honzawa does not teach or suggest, as acknowledged by the Examiner, pressing a detector directly against the filling opening. Office Action dated April 20, 2004, page 4.

Honzawa also does not teach or suggest measuring the light emitted from the chamber when the detector is pressed against the filling opening to provide a first reading, illuminating a light source external to the chamber, measuring the light emitted from the chamber with the light source illuminated to provide a second reading, and comparing the first reading and the second reading to determine the light-tightness of the chamber. Rather, Honzawa discloses a manual chemiluminescence measuring apparatus including a box-like housing 1 having an opening 15 at a top surface, a cover 6 provided at the top surface having a through hole that allows a distal end of a syringe 42 containing a luminous reagent to be introduced into the interior of the housing, a hollow chamber 33 with a side wall opening 38 being disposed in the housing and partially enclosing a micro-sample tube 21 containing a sample solution, and a photo-sensing unit 40 being disposed in the housing for detecting luminescence from the micro-sample tube via the opening 38 of the hollow chamber 33. Col. 1, lines 51-67; Col. 2, lines 1-3. The hollow chamber 33 includes a rotating cylindrical hollow chamber 370 having an opening 37. Col. 5, lines 41-44. The optical path between the photo-sensing unit 40 and the micro-sample tube 21 is opened when the position of the opening 38 and the position of the opening 37 coincide with each other. Col. 5, lines 44-47. Honzawa does not disclose the acts of illuminating a light

source external to the chamber, taking a plurality of readings, and comparing the readings to determine light-tightness of a chamber.

Zavislan does not cure the deficiencies of Uzan, Berthold, Smethers, and Honzawa. Zavislan does not teach or suggest pressing a detector directly against the filling opening, measuring the light emitted from the chamber when the detector is pressed against the filling opening to provide a first reading, measuring the light emitted from the chamber with the light source illuminated to provide a second reading, and comparing the first reading and the second reading to determine the light-tightness of the chamber. Rather, Zavislan discloses a spectrophotometer including electrical components mounted in a module 260. Col. 10, lines 13-15. The module 260 is supported within a housing 262. Col. 10, lines 15-16. The module 260 includes a wall 74 having an extension 264. Col. 10, lines 16-17. The extension 260 includes a first cavity 266 that supports a lamp 268 and a second cavity 270 that supports a cuvette 271. Col. 10, lines 17-19. The walls of the cuvette 271 are transparent, and the cuvette 271 includes an opaque cover 274, which pivots downwardly to close the cuvette 271. Col. 10, lines 20-22. Upon closure of the cover 274, the lamp 268 is illuminated and projects through the sample in the cuvette 271 for spectral measurement. Col. 10, lines 22-30; Fig. 23. Zavislan does not disclose the acts of taking a plurality of readings and comparing the readings to determine light-tightness of a chamber.

Additionally, there is no suggestion or motivation to combine the five asserted reference teachings. First, there is no suggestion to combine the teachings of Uzan with Berthold, Smethers, and Honzawa because the Uzan apparatus is designed specifically for absorbency measurements. The reaction modules in Uzan are transparent so that light from a light beam can pass through each reaction well to a detector. Col. 7, lines 6-23. In contrast, the devices of Berthold, Smethers, and Honzawa are designed to measure emission rather than absorbency. Emission studies require that ambient light be reduced as much as possible from the detector during analysis. Therefore, Berthold, Smethers, and Honzawa teach away from Uzan because the devices of Berthold, Smethers, and Honzawa teach specific ways to attempt to reduce the ambient light around a particular sample being tested. Furthermore, creating an automated system to measure emission rather than absorbency requires a sophisticated detector system and reaction vessel so that a dark chamber can be formed with each reaction well as the vessel passes by the detector during transport along a path.

In addition, there is no suggestion to combine the teachings of Uzan with Berthold, Smethers, Honzawa, and Zavislan because Uzan teaches an automatic apparatus for immunological assay. The devices in Berthold, Smethers, Honzawa, and Zavislan are not automatic systems and the unique operation of each device cannot be modified for use in the automatic apparatus of Uzan. Each device of Berthold, Smethers, Honzawa, and Zavislan require a unique structure for its respective operation.

Second, there is no suggestion to combine the teachings of Zavislan with Berthold, Smethers, and Honzawa because the Zavislan device is a spectrophotometer, which measures optical density or spectral absorption. These measurements require that a light beam be projected through the test sample to a photodetector. In contrast, the devices of Berthold, Smethers, and Honzawa reject the notion of additional light as discussed above. Therefore, Zavislan teaches away from being combined with Berthold, Smethers, and Honzawa.

The Examiner indicated in the Advisory Action that "Zavislan only need teach an opaque cover... and by combining the opaque cover of Zavislan with the other references, one arrives at the claimed invention." The opaque cover of Zavislan does not satisfy the claimed requirement of a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device. In addition and as noted above, there is no suggestion or motivation to combine the teachings of Zavislan with Berthold, Smethers, and Honzawa.

The Examiner further indicated in the Advisory Action that "one would have been motivated to use the opaque cover of Zavislan because it ensures the elimination of unwanted light (light other than that from the excitation source) from passing through the sample." The Examiner may be correct in this statement, but the Examiner cannot ignore the fact that the purpose of the Zavislan device requires that light pass through the test sample and through the transparent wall of the cuvette, in order to get a measurement. The Examiner must consider the prior art reference as a whole, including portions that would lead away from the claimed invention. M.P.E.P. § 2141.02. As noted above, there is no suggestion or motivation to combine the teachings of Zavislan with Berthold, Smethers, and Honzawa.

Accordingly, the Examiner has not presented a *prima facie* case of obviousness because the prior art references when combined do not teach or suggest all of the claim limitations.

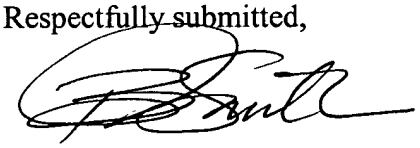
Specifically, the Examiner has not identified a reference or combination of references that disclose a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device.

For at least the reasons noted above, Uzan combined with Berthold, Smethers, Honzawa, and Zavislan does not teach or suggest the subject matter of Claim 23. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 23 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, Claim 23 is allowable.

CONCLUSION

In view of the foregoing, reversal of the final rejection of Claims 16-17, 19-21, and 23 and allowance of Claims 16-17, 19-21, and 23 are respectfully requested.

Respectfully submitted,



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APPENDIX

1-5. (Canceled)

6. The apparatus according to claim 11, including an opaque shoe for pressing in light-proof manner around the window of the vessel provided with the filling opening for passing light between the vessel and the photometric means.

7. The apparatus according to claim 11, including a plate for receiving the washing means and the photometric means.

8. The apparatus according to claim 11, wherein the photometric means include moving equipment for pressing the shoe against the window of the vessel.

9. The apparatus according to claim 11, including a shutter for optically isolating a photoelectric detector and means for measuring electrical values delivered by the photoelectric detector while it is immersed in the dark, the shutter being closed.

10. The apparatus according to claim 9, wherein movement of moving equipment serves to close or open the shutter.

11. An automatic apparatus for immunological assay, the apparatus comprising:

means for supporting, guiding, and stepwise displacement of vessels, or of sets of reaction vessels along a path having a predetermined number of positions,

means for supporting samples to be analyzed,

means for supporting reagents,

means for taking determined quantities of samples and of reagents and for injecting the quantities taken into the reaction vessels,

means for washing the vessels,

means for reading results,

means for feeding the sets of reaction vessels and for ejecting the sets of vessels,

means for forming a temporary dark chamber with the vessel, the temporary dark chamber being proof against external light,

photometric means for measuring an intensity of light, wherein the vessel includes walls for receiving a sample to be tested, a test reagent, and a substrate coupled with a chemiluminescent substance, and

a filling opening, wherein the walls are proof against any light emitted by the chemiluminescent substance, apart from a window for reading the intensity of any light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate, and wherein the window corresponds to the filling opening of the vessel and wherein the window is surrounded by a substantially plane zone against which a light-proof shoe is pressed, and

a light source for illuminating, on command, outside of the dark chamber, and

a photometric means so as to enable the dark chamber to be tested for light-tightness, the immunological assay being rejected if the photometric means detects light emitted by the light source.

12-14. (Canceled)

15. The apparatus according to claim 9, wherein the photoelectric detector is a photomultiplier.

16. A reaction vessel assembly for an automatic chemiluminescence measuring apparatus for immunological assay which includes a photometric device, the assembly comprising:

a vessel comprising walls for receiving a sample to be tested, a test reagent, and a substrate coupled with a chemiluminescent substance, and a filling opening, wherein the walls are proof against any light emitted by the chemiluminescent substance, and the filling opening corresponds to a window for reading an intensity of any light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate, and wherein the filling opening is completely surrounded by a planar rim; and

a light-proof shoe that is proof against external light and that is directly pressed against the planar rim to form a temporary dark chamber, the shoe being provided with a central opening for passing light between the vessel and the photometric device.

17. An automated chemiluminescent apparatus for immunological assay, the apparatus comprising:

means for supporting, guiding, and stepwise displacement of vessels, or of sets of reaction vessels along a path having a predetermined number of positions,

means for supporting samples to be analyzed,

means for supporting reagents,

means for taking determined quantities of samples and of reagents and for injecting the quantities taken into the reaction vessels,

means for washing the vessels,

means for reading a result,

means for feeding the sets of reaction vessels and for ejecting the sets of vessels,

means for forming a temporary dark chamber with the vessel, the temporary dark chamber being proof against external light, the dark chamber having photometric means for measuring an intensity of light, wherein the vessel includes

walls for receiving a sample to be tested, a test reagent, and a substrate coupled with a chemiluminescent substance, and

a filling opening, wherein the walls are proof against any light emitted by the chemiluminescent substance, and the filling opening corresponds to a window for reading the intensity of any light emitted by a reaction mixture formed by the sample to be tested, the reagent, and the substrate, wherein the filling opening is completely surrounded by a planar rim, and

a light proof shoe provided with a central opening for passing light between the vessel and the photometric means and being directly pressed against the planar rim.

18. (Canceled)

19. The apparatus according to claim 17, including a plate for receiving the washing means and the photometric means.

20. The apparatus according to claim 17, wherein the photometric means include moving equipment for pressing the shoe against the window of the vessel.

21. The apparatus according to claim 17, including a shutter for optically isolating a photoelectric detector and means for measuring electrical values delivered by the photoelectric detector while it is immersed in the dark, the shutter being closed.

22. (Canceled)

23. A method for performing immunological assays that detects light emitted by a reaction mixture consisting of a sample, a reagent and a chemiluminescent substance, said method being performed with an automated chemiluminescent apparatus as set forth in claim 17, said method comprising:

combining a sample and a reagent in a chamber of the reaction vessel having a filling opening;

adding a chemiluminescent substance to the chamber;

pressing a detector directly against the filling opening;

measuring the light emitted from the chamber when the detector is pressed against the filling opening to provide a first reading;

illuminating a light source external to the chamber;

measuring the light emitted from the chamber with the light source illuminated to provide a second reading; and

comparing the first reading and the second reading to determine the light-tightness of the chamber.

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